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| APPLICATION NO.           | FIL     | ING DATE            | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---------------------------|---------|---------------------|----------------------|-------------------------|------------------|
| 09/998,195 12/03/2001     |         | Chris H. Senanayake | 4821-409-999         | 4449                    |                  |
| 20582                     | 7590    | 09/08/2003          |                      |                         |                  |
| PENNIE &                  |         | OS LLP              | EXAMINER             |                         |                  |
| 1667 K STRI<br>SUITE 1000 |         | 20006               |                      | BARTS, SA               | MUEL A           |
| WASHINGT                  | ON, DC. | 20006               |                      | ART UNIT                | PAPER NUMBER     |
|                           |         |                     |                      | 1621                    | 7                |
|                           |         |                     |                      | DATE MAILED: 09/08/2003 | 10               |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.           | Applicant(s)  |  |  |  |  |  |
|---|---------------------------|---|--|--|--|--|--|
|   | 09/998,195                | SENANAYAKE  |  |  |  |  |  |
| Offic Action Summary  | Examiner                  | Art Unit  |  |  |  |  |  |
|   | Samuel A Barts            | 1621  |  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |                           |   |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of Ihis communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of Ihis communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                           |   |  |  |  |  |  |
| Status  |                           |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on _  |                           |   |  |  |  |  |  |
| , <u> </u>  | This action is non-final. |   |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  |                           |   |  |  |  |  |  |
| 4) Claim(s) 1-73 is/are pending in the application.   |                           |   |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |                           |   |  |  |  |  |  |
| 5) Claim(s)is/are allowed.  |                           |   |  |  |  |  |  |
| 6) Claim(s) is/are rejected.  |                           |   |  |  |  |  |  |
| 7) Claim(s) is/are objected to.   |                           |   |  |  |  |  |  |
| 8) Claim(s) 1-73 are subject to restriction and/or election requirement.  |                           |   |  |  |  |  |  |
| Application Papers  |                           |   |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |                           |   |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |                           |   |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.   |                           |   |  |  |  |  |  |
| 11) The proposed drawing correction filed on  |                           | oved by the Examiner.                                   |  |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |                           |   |  |  |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |                           |   |  |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |                           |   |  |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |                           |   |  |  |  |  |  |
| a) All b) Some * c) None of:  |                           |   |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |                           |   |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |                           |   |  |  |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |                           |   |  |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |                           |   |  |  |  |  |  |
| a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |                           |   |  |  |  |  |  |
| Attachment(s)   |                           |   |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)   | 5) Notice of Informal     | y (PTO-413) Paper No(s)<br>Patent Application (PTO-152) |  |  |  |  |  |
| J.S. Patent and Trademark Office  |                           |   |  |  |  |  |  |

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## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-8 and 32-43, drawn to compounds, classified in class 564, subclass 305.
  - II. Claims 9-31 drawn to method of treatment, classified in class in class514, subclass 646
  - III. Claims 44-59, drawn to a process of making compounds, classified in class in class 564, subclass 305.
  - IV. Claims 60-66, and 71are drawn to compounds, classified in classes 564, 558 and 568
  - V. Claims 67-70 are drawn a process of making compounds, classified in class in class 564 subclass 305+
  - VI. Claims 72-73 are drawn a process of making compounds, classified in class in class 564 subclass 80+

The inventions are distinct, each from the other because of the following reasons:

2. Inventions {III, V, and VI} and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as

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claimed can be made by another and materially different process. Applicant is reminded that should the product be elected and found allowable, the claims corresponding to the process of making the same compound will be rejoined.

- 3. Inventions {II, IV, V} are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together and they have different modes of operation
- 4. Inventions {III, IV, V} are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together and they have different modes of operation
- 5. Inventions IV and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process. Applicant is reminded that should the product be elected and found allowable, the claims corresponding to the process of making the same compound will be rejoined.

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6. Inventions {III, IV, V} are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together and they have different modes of operation

- 7. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product.
- 8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 9. Claims 60-66, and 71are drawn to plurality of disclosed patentably distinct species comprising each the individual compound of each individual claims. Applicant is required under 35 U.S.C. 121 to elect a compound, even though this requirement is traversed.
- 10. Claims 1-8, and 32-43 are drawn to plurality of disclosed patentably distinct species comprising for examples compounds disclosed in the specification. Applicant

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is required under 35 U.S.C. 121 to elect a compound, even though this requirement is traversed.

Should applicant traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. A telephone call was made to Mr. Dean Fanelli on 9/2/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel A Barts whose telephone number is 703-308-4630. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johan Richter can be reached on 308-1235. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Samuel A Barts Primary Examiner Art Unit 1621

s.b.